

**Synopsis:** As the Board of Health considers secure medicine return, it must define who may utilize the producer-provided medicine take-back system. Residents of the county are clearly intended users of the system, however description is needed for additional settings where residents are likely to generate waste medicines.

**Generators of Pharmaceutical Waste & the Regulatory Context:**

Pharmaceutical waste is generated by individuals (patients), by doctor’s offices, by hospitals, by pharmacies, by nursing homes and other residential care facilities, and by various other businesses. Medicine take-back programs typically focus on disposal of unwanted and expired medicines from residential generators. Business generators of pharmaceutical waste are regulated under federal and state laws. However the categories of residential generators and business generators do not have clear distinctions in some situations.

Residential sources: Residents in the county currently lack sufficient access to secure medicine take-back programs, as described in other staff reports to the Board of Health and the Subcommittee on Secure Medicine Return.

Business sources: Federal and state regulations govern disposal of pharmaceutical waste from clinics, hospitals, pharmacies or other business generators. Leftover, expired, or otherwise unusable medicines from business sources must be disposed of properly as either hazardous waste or dangerous waste. Businesses contract with reverse distributors or pharmaceutical waste disposal companies to handle pharmaceutical wastes, typically at appropriately permitted high temperature incinerators.

Harder to categorize sources: In some settings, waste medicines may be categorized as business waste or as residential waste depending on how the waste was generated— such as in some long-term care facilities, residential boarding homes for elders or the disabled, schools, and day cares. In such settings, leftover medicines that are owned, controlled, and dispensed by the facility would be business waste. But leftover medicines that are owned by residents or individuals would be considered residential waste.

Long-term care facilities (LTCF) include a wide range of institutions, from large nursing homes with skilled nursing professionals that function similarly to hospitals to small family-homes and other small assisted-living facilities without skilled nursing care. In some of these facilities, controlled substances and other medicines are owned by the resident, and this situation has presented a significant dilemma for safe and legal disposal of leftover drugs. Sometimes staff at these facilities are left with a resident’s medicines, without acceptable means for disposing of them.

Addressing part of this dilemma, the DEA’s proposed rule for collection of controlled substances would authorize LTCF’s to dispose of controlled substances for their residents only when a secure collection receptacle is operated on the LTCF’s premises by an authorized retail pharmacy. If a LTCF does not have a collection receptacle, then the resident may dispose of their own medicines through a take-back program. Or if the resident dies, an individual authorized to dispose of their property may utilize a take-back program.

Considerations for this decision include:

- The entities currently lacking access to safe disposal services for pharmaceutical waste.
- Federal and state laws and regulations for disposal of waste pharmaceuticals from business sources.
- Provisions of the DEA’s proposed rule for secure disposal of controlled substances from long-term care facilities.

**Policy decision to be made:**

Define who is allowed to use the medicine take-back system, i.e. residents and any other appropriate generators of waste medicines. Identify any sources of waste medicines that are excluded from using the program.

Proposal for consideration:

Define the following as “covered entities” who may utilize the medicine take-back program to return “covered drugs”:

- Residents of King County, including single and multiple family residences.
- People returning drugs from locations where household medicines are unused, unwanted, disposed of, and abandoned, such as schools and day cares.
- People returning drugs from long-term care facilities, hospice services, adult homes, and boarding homes where people reside on a temporary or permanent basis and where residents maintain ownership of prescription medicines prescribed to them or over-the-counter medicines purchased for them.

“Covered entities” does not include business generators of pharmaceutical waste, such as:

- Hospitals, clinics, doctor’s offices, veterinarian clinics;
- Pharmacies;
- Airport security and law enforcement drug seizures;
- Other nonresidential or business sources of pharmaceutical waste as determined by the Department.

---

*Attachments:*

- Summary of provisions in DEA’s proposed rule for disposal of controlled substances from long-term care facilities.
- “About Disposal of Waste Medicines from Residential Medicine Take-back Programs”, handout to Secure Medicine Return Subcommittee on August 16, 2012.
- *Policy Comparison Table: #2 “Users of the program (covered entities)”*